

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Allan PATTERSON et al

Serial No: 09/159,680

Group Art Unit: 1614

Filed: September 24, 1998

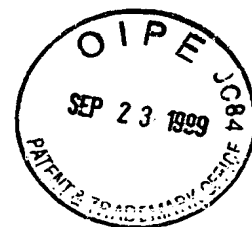
Examiner: J Goldberg

For: LONG-ACTING OXYTETRACYCLINE COMPOSITION

RECEIVED
TECH CENTER 1600/2900
99 SEP 27 AM 10:37

SUPPLEMENTARY DECLARATION OF SEAN DUFFY UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231



Sir:

The undersigned, Sean Duffy, declares that:

he is Project Manager of Research and Development for Norbrook Laboratories Limited, a company having rights in the above-identified patent application;

he is a citizen of Ireland residing at 57 Tullinavall Road, Cullyhanna, Newry, Co Down;

he has reviewed the above-identified US patent application and understands the invention claimed therein;

he is familiar with the art to which the claimed invention is directed, having received the Degree of Bachelor of Science in Biochemistry (School of Biochemistry, The Queen's University of Belfast), Year of Degree: 1988 and Degree of Doctor of Philosophy (School of Medicine, The Queen's University of Belfast), Year of Degree: 1991, and having been employed in that art for 8 years;

in connection with his studies and work in that art, he has developed an understanding as to the level of skill of one having ordinary skill in the art at the time the invention in the above-identified application was made;

he has reviewed and understands the references of record in the present application, namely Malook *et al* (US Patent No 4,772,460), Zupan *et al* (US Patent No 5,075,295) and the European reference (European Patent Application No 0,038,013);

that having made and signed a declaration under 37 C.F.R. § 1.132 that was filed in the above identified application on March 16, 1999, he now declares as follows;

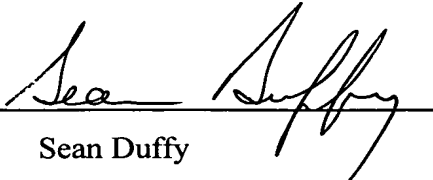
the percent of ingredients present in Examples A and B are as shown below

Sample A and B - Formulation Details

Oxytetracycline	30% w/v
Magnesium oxide	2.7% w/v
Sodium formaldehyde sulfoxylate	0.4% w/v
Glycerol formal	40% v/v
Polyethylene glycol 200	10% v/v
Monoethanolamine	q.s. pH 8.6 to 8.8
Water	ad 100% v/v

and further, samples A and B were manufactured according to the above formulation which is consistent with the claims of the present patent application. Sample A was manufactured in 1996 and Sample B was manufactured at the time of assessment of Formulations (1) and (2) after five months storage at room temperature. This provided for a direct comparison between Formulations (1) and (2) with a fresh and aged sample of the composition of the present invention. From the results of the determination of appearance, syringeability and viscosity after five months storage at room temperature, it is evidence that Formulations (1) and (2) would have no commercial potential whatever which is in agreement with the conclusion arrived at upon initial manufacture of these formulations. In contrast however, Samples A (aged) and B (fresh) performed well with respect to appearance, syringeability and viscosity highlighting the commercial potential of such formulations.

He further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such wilful false statements may jeopardise the validity of the application or any patent issuing thereon.

Signed: 
Sean Duffy

Date: 31st August 1999.